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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 05 NOV 2004

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Applicant's or agent's file reference GDM/JR-M020103-WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No. PCT/GB 03/03393	International filing date (day/month/year) 04.08.2003	Priority date (day/month/year) 02.08.2002
International Patent Classification (IPC) or both national classification and IPC A61L31/14		
Applicant RALINEA LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 28.01.2004	Date of completion of this report 08.11.2004
Name and mailing address of the international examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Heck, G Telephone No. +31 70 340-3288



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB 03/03393

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-24, 26-28 as originally filed
— 25 received on 30.10.2003 with letter of 30.10.2003

Claims, Numbers

1-12 as originally filed

Drawings, Sheets

1/15-15/15 received on 30.09.2003 with letter of 30.09.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,

- claims Nos. 12

because:

- the said international application, or the said claims Nos. 12 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- the written form has not been furnished or does not comply with the Standard.

- the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-11
	No: Claims	-
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-11
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	-

2. Citations and explanations

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**INTERNATIONAL PRELIMINARY
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International application No. **PCT/GB 03/03393**

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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/03393

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Since claim 12 is directed to a method of treatment of the human or animal body by surgery, it relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. For the assessment of the subject-matter of present claim 12 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. Therefore, no opinion will be formulated with respect to the subject-matter of claim 12 (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document (D1) cited in the International search report:

D1 ... US 5,108,413 A (Moyers R.E.)

Document D1 discloses (cf. claims 1, 2, 10, 11) a dilator for opening the lumen of a tubular organ comprising an elongated flexible expansion member of a material having a negative Poisson ratio. The subject-matter of claims 1-11 of the present application differs from the disclosure of D1 in that both ends of the tubular liner are open and is therefore novel according to Article 33(2) PCT.

Document D1, which is considered the most relevant state of the art, discloses (cf. col. 1, lines 43-45 ; claims 1, 2, 10, 11) a dilator for opening the lumen of a tubular body organ comprising an elongated flexible expansion member of a material having a negative Poisson ratio to obtain a known and controllable radial expansion.

In view of D1, the objective technical problem underlying the present application is considered to provide devices for lining *in vivo* ducts which allow for a known and controllable radial expansion.

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**INTERNATIONAL PRELIMINARY
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International application No. PCT/GB 03/03393

The solution is a tubular liner for insertion into an *in vivo* duct with two open ends to allow for fluid flow through the liner comprising an auxetic material.

The subject-matter of claims 1-11 of the present application is not limited to implantable or biocompatible liners. According to the Applicant, there is no reason why the teaching of this document should be limited to *in vivo* ducts.

According to the preliminary examination authority, the limitation to *in vivo* ducts is essential. The application does not contain any mention of other types of ducts and it is not apparent how the application of the tubular liner to other types of ducts would be useful.

Therefore, the objective technical problem has been defined above as to provide devices for lining *in vivo* ducts so that the technical problem is not solved over the whole scope of the claims.

Since this objective technical problem is not solved over the whole scope of the claims, the subject-matter of claims 1-11 cannot be considered to involve an inventive activity according to Article 33(3) PCT.

The subject-matter of claims 1-11 of the present application fulfils the requirements of Article 33(4) PCT concerning the industrial applicability.

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